No. 610

IN THE

United States Court of Appeals

FOR THE THIRD CIRCUIT

Case No. 10765

ATLAS POWDER COMPANY, a Corporation, *Petitioner,*

v.

OSCAR R. EWING, Federal Security Administrator, *Respondent.*

PETITION FOR REVIEW OF AN ORDER OF THE FEDERAL SECURITY ADMINISTRATOR

REPLY BRIEF FOR PETITIONER

OSCAR COX
1210 18th Street, N. W.
Washington 6, D. C.
Attorney for Petitioner

C. C. GAMMONS,
KENNETH E. MULFORD,
ROGER R. HORTON,
Delaware Trust Co. Bldg.,
Wilmington, Delaware.
LLOYD N. CUTLER,
LOUIS F. OBERDORFER,
HERBERT L. PACKER,
DONALD F. TURNER,
1210 18th Street, N. W.,
Washington 6, D. C.,
Of Counsel.

TABLE OF CONTENTS

PAGE

INTRODUCTION 1

POINT I—

The Administrator's order is obviously and materially ambiguous and should be remanded if the Court finds that the Administrator erred on either of the two grounds which he stated for excluding our products from bread 6

POINT II—

The Administrator's finding that the Atlas products are deceptive while the competing products are non-deceptive is not supported by substantial evidence and is illegally discriminatory.. 8

POINT III—

The Administrator has no statutory power to exclude a proposed ingredient as to which he finds there is no definite evidence of injury, on the ground that its proponent has failed to prove that there is "no likelihood of injury" to persons consuming the ingredient over a life span 13

POINT IV—

The Administrator has failed to justify his discrimination between our products and the competing products on the issue of safety 16

PAGE

POINT V—

The hearing should be reopened to consider the laboratory experiments on the safety of our products which the Food and Drug Administration has been conducting since 1948 22

CONCLUSION 26

APPENDIX

Correspondence between counsel for Atlas Powder Company and counsel for the Administrator with respect to laboratory experiments on the safety of the Atlas products conducted by the Food and Drug Administration 1a

AUTHORITIES CITED

CASES: PAGE

Cream Wipt Food Products Co. v. *Federal Security Administrator,* 187 F. 2d 789 ..... 11, 12

Federal Security Administrator v. *Quaker Oats Co.,* 318 U. S. 218, 63 S. Ct. 589 (1943) 14

Fogarty v. *United States,* 340 U. S. 8, 71 S. Ct. 5 (1950) 15

Holloway v. *Dunham,* 170 U. S. 615, 18 S. Ct. 784 (1898) 7

Interstate Commerce Commission v. *Jersey City,* 322 U. S. 503, 64 S. Ct. 1129 (1944) 28

National Labor Relations Board v. *Jarka Corp.,* No. 10715 (C. A. 3, August 15, 1952) 7

United States v. *United Mine Workers,* 330 U. S. 258, 67 S. Ct. 677 (1947) 15

STATUTES, ETC.:

Federal Food, Drug and Cosmetic Act, 52 Stat. 1040 *et seq.,* 21 U. S. C. A. § 301, *et seq.*

Section 401 13

402(a)(1) 14

402(a)(2) 14

701(f)(2) 26, 27, 28

H. R. Rep. No. 3254, 81st Cong., 2d Sess. 10 (1951) 15

MISCELLANEOUS:

Crawford, *The Food and Drug Administration's Viewpoint on Chemicals in Foods,* 7 Food Drug Cosmetic Law Journal 85 (1952) 18

Annual Report of the Federal Security Agency, Food and Drug Administration 17 (1951) 25

INTRODUCTION

Our three principal comments on the Administrator's Brief are:

(1) It does not focus on the precise form of relief for which we pray.

(2) It tries to cover the inadequacy of the Administrator's safety findings to support the exclusion of our products by interpreting the evidence in ways which are not corroborated by the findings themselves.

(3) It fails to advance any convincing reason justifying the Administrator's plain discrimination against the Atlas products, in favor of the competing classes of surface-active agents.

First. As regards relief, we do not ask this Court to "weigh the evidence, rewrite the findings and reach an independent expert conclusion on a mass of scientific evidence." (Compare *Administrator's Brief, p. 36*). We do not ask this Court to invade the areas of the Administrator's special competence. What we do ask is that this Court exercise its specific statutory authority to reverse and to remand the Administrator's findings and order, and to direct a reopening of the hearing which the Administrator closed more than three years ago, 32 months before he entered his final order.

We are entitled to a remand because, on the record as it stands, the Administrator's findings and order, so far as they affect the use of Atlas products in bread, are ambiguous, unsupported by substantial evidence, illegally discriminatory and in excess of the power granted to him by Congress.

We are entitled to a reopened hearing, upon remand, to consider additional material evidence about the safety of all surface-active agents, including the tests conducted by the Food and Drug Administration itself, and to consider the additional evidence which conclusively demonstrates that the competing classes of surface-active agents cannot properly be found non-deceptive at normal levels of use unless a similar finding of non-deception is made for the Atlas products.

Second. The Administrator's Brief makes a bogey man attempt to communicate the idea that our products are "poison." By contrast, his plain *finding* is that (on the basis of the evidence adduced at the hearings which closed more than three years ago) "the record shows no definite evidence of injury from the use" of the Atlas products "in amounts in which they are likely to occur in the diet from their use in bread." *A. 473.* In those hearings there was no clinical or any other evidence that a single human being had suffered any injury at all from the use of the Atlas products, although they had been used in billions of loaves of bread consumed by millions of people. Tests on human beings conducted on the Atlas products by competent medical men such as Dr. Perry Culver of the Massachusetts General Hospital and the Harvard Medical School, and introduced in the hearings, showed no evidence of any injury

and no evidence of any acute or chronic toxicity. *A. 470-1.* In all of the animal feeding tests conducted on the Atlas products not only by Atlas-sponsored scientists, but also by scientists sponsored by our competitors who were obviously trying to keep the Atlas products out of bread, there was no basis on which the Administrator could find that there was or might be evidence of injury from their use in the amounts likely to be consumed in bread, and he did not so find. *A. 469, 472.* Despite the fact that counsel for the Administrator in his Brief now attempts to stretch the evidence and treat it in such a way as to make new findings, and to imply that the Administrator found that our products are not safe, the fact is that the Administrator himself found no evidence of injury from the use of Atlas products in the amounts likely to be consumed in bread, and he did not find that the Atlas products would or might cause injury. *A. 472-3.*

The Administrator, although he found no evidence of injury from the use of the Atlas products and did not find them unsafe, nevertheless proceeded to hold that Atlas had failed to meet a virtually absolute negative test set up by him for the first time in the administration of the Act. He said that "the results of the pharmacological tests reported do not warrant the conclusion that there is no likelihood of injury from bread containing these substances in the amount proposed to persons consuming it continuously over a life span." *A. 473.* This negative finding is not the equivalent of an affirmative finding that our products are unsafe. Such an affirmative finding is the only lawful foundation for a decision to exclude our products from bread on the ground of safety. The unsupported arguments in the Ad-

ministrator's Brief are not effective substitutes for a lawful finding.

Third. The illegal discrimination which the Administrator has practiced appears from the face of his own findings in support of this order. The efforts of his counsel to amend the findings in this respect are unsuccessful. The Administrator's findings, order and memorandum opinion considered three types of products—the Atlas product (Myrj 45), the Swift and Co. product (mono- and diglycerides) and the Hachmeister Co. product (diacetyl tartaric acid esters). With respect to all three products the Administrator found that:

(1) They have the capacity to make bread feel soft and, therefore, deceptive to consumers.

(2) They are all "surface-active" agents.

(3) Surface-activity, common to them all, raise a common question as to their safety.

(4) No final judgment could, at that time, be made about the safety of any of the three products for use over the life span.

The Administrator illegally discriminated because, having found all three products to be identical in four crucial respects, he decided to admit two surface-active agents (mono- and diglycerides and diacetyl tartaric acid esters) into the bread standard at restricted levels pending a reopened hearing as to their safety, and to exclude the Atlas products at any level. He refused to reopen the record to

consider evidence as to our products, or to admit us temporarily pending a reopening hearing.

The crowning example of discrimination is the Administrator's action with respect to diacetyl tartaric acid esters. In the Administrator's tentative order he excluded the diacetyl product on substantially the same safety grounds as he excluded our products. *A. 8.* In his final order, he admitted the diacetyl product to the standard by taking account of evidence admittedly outside the record presented to him after the hearings ended. *A. 463.* At the same time he refused to admit our products and refused to consider additional evidence accumulated after the close of the hearings.

We do not say that the Administrator made a mistake in admitting those products to the standard although the last word has not yet been said as to their safety, as indeed the last word has not yet been said on many other useful items long accepted as ingredients of our diet. His mistake was in ruling our products out, while admitting the competing products, with no substantial basis, in or out of the record, for this discrimination, which closes down our business and forfeits our market to our competitors.

In this Reply Brief we shall demonstrate the failure of the Administrator's Brief to repair his case on any of the crucial issues in this proceeding.

POINT I.

The Administrator's order is obviously and materially ambiguous and should be remanded if the Court finds that the Administrator erred on either of the two grounds which he stated for excluding our products from bread.

The Administrator's Brief now takes the position that his findings on safety and deception were independent grounds for the exclusion of our products, and that the ultimate finding must stand if he was right on either of these grounds regardless of any error he committed on the other. *Administrator's Brief, p. 33.*

This position is inconsistent not only with the plain language of the findings, but also with the Administrator's action, taken concurrently with the issuance of his order, in denying our Motion to Reopen. At that time he stated that he might reconsider the question of a reopening after we "completed" the experimental work on the *safety* of our products. *A. 483-4.* In a letter dated May 12, 1952, he advised Atlas that he did not "believe that Atlas type products should be permitted to be used in bread *pending* the completion of further investigational work." *A. 457.* (Emphasis added.)

The plain implication of what the Administrator said is that he might be willing to alter his ultimate conclusion about the suitability of our materials on the basis of a further showing as to their safety. Obviously, if the Administrator meant that the ground of deception was of itself sufficient to exclude our products, his invitation to carry out further expensive and time-consuming studies on safety was a trap rather than the helpful suggestion ostensibly intended. It is more likely that the Administator's invitation meant what it said.

Similarly, if the Administrator had not erred in finding that the Atlas products deceive, the Administrator's findings indicate that he might have approved at least the temporary use of the Atlas products, despite his doubts as to the sufficiency of the proof as to their safety. Once the Administrator had determined that the mono- and diglycerides and the diacetyl tartaric acid esters did not deceive, he decided to permit their temporary use notwithstanding his specific finding that the safety of these materials over the life span had not yet been proved. With the findings in their present ambiguous state, this Court cannot tell whether or not the Administrator would have reached the same decision as to the Atlas products, if he had not erroneously found that the Atlas products deceive.

As we have shown in our main brief (pp. 15-18), it follows that if either of the two stated interdependent grounds for the exclusion of our products is erroneous, this Court must reverse and remand the case for further hearings. In an attempt to avoid this necessary conclusion, the Administrator has cited several decisions. Two of these decisions may fairly be cited for the proposition that where a finding is made on two grounds, *either* of which is sufficient to support the finding, it does not matter that one ground is wrong.* But reliance on those cases begs the question presented here, which is whether a decision based on two grounds can be sustained when one ground is wrong and when the record indicates that the Administrator might have arrived at a different result if the error had not been made.

**National Labor Relations Board* v. *Jarka Corp.*, No. 10715, (C. A. 3, August 15, 1952); *Holloway* v. *Dunham*, 170 U. S. 615, 618 (1898). The Administrator also cites in a footnote two additional decisions whose relevance to this question is not apparent to us. *Administrator's Brief, p. 35, n. 44.*

POINT II.

The Administrator's finding that the Atlas Products are deceptive while the competing products are non-deceptive is not supported by substantial evidence and is illegally discriminatory.

The Administrator's discrimination between our products and the mono- and diglycerides on the issue of deception is unsupportable. He first suggests that there is a basis for treating them differently because the mono- and diglycerides perform functions in bread which our products do not perform.* The Administrator does not dispute that both classes of products retard staling and prolong softness; and it is this common characteristic—not others which they may not share—that gives rise to the charge of deception. It is also this common characteristic which brings the two classes of products into economic competition, and which explains the intensive efforts of Swift & Co. at the bread hearings to bring about the exclusion of the Atlas products from bread.

There is, of course, a basic question, which the Administrator has nowhere answered, whether our products or the competing products deceive consumers any more than

*The evidence of record showed that Myrj 45 not only makes bread feel softer in the grocery store, but also causes the bread to stay softer and fresher for a longer period of time after the wrapper is opened and use begins, retaining palatability even though consumption is spread over a period of several days. *A. 2828, 2878, 2881.* The evidence of record also showed that Myrj 45 improves the machining and handling qualities of the bread dough and the texture of the finished product. *A. 736.* While these functions are not identical to the functions of the mono- and diglycerides, they are very similar, and they are important and useful functions entirely apart from the function (shared by the mono- and diglycerides) of making the bread feel softer on the grocery shelf.

do the air-tight cellophane wrappers, which also keep bread softer for a longer period. However that may be, the Administrator does not seriously dispute that the charge of deception, if applicable at all, is applicable to both classes of products. Instead, he tries to justify the result by picking a level—20% of the shortening content of bread—at which he says the mono- and diglycerides do not deceive. He now admits that the only basis in a 17,000 page record for this finding is the testimony of Dr. Bradley. *Administrator's Brief, pp. 63-64.*

In our main brief (pp. 23-26) we showed that Dr. Bradley's testimony on this point was based on his erroneous recollection that certain "high ratio" shortenings mentioned at the 1941 hearings contained 20% mono- and diglycerides. As a matter of fact, "high ratio" shortenings contained from 4 to 10% mono- and diglycerides. When confronted with this fact, Dr. Bradley not only admitted that his recollection, and therefore his 20% figure, was wrong. He specifically stated that he had *no* basis on which to set an upper limit on the use of mono- and diglycerides.

The Administrator's only reply is to point out an earlier Bradley reference to a 20% level. Both references occurred on the same day. A fair reading of Bradley's entire testimony shows that *both* his references to a 20% level were based on his erroneous recollection of the mono- and diglyceride content of "high ratio" shortenings. *A. 693-4, 706.* And whatever the basis for Dr. Bradley's mention of the 20% figure, he completely retracted his testimony. On the very next day he admitted not once, but twice, that he had had no basis at all on which to set an upper limit for the use of mono- and diglycerides.

The first admission came in answer to questions by counsel for Atlas:

> "Q. In that answer on 5857, you refer to statements which you made earlier concerning these shortenings and you seem to be basing some of your opinions on those shortenings.
>
> "It is not clear to me, and I wonder if you would clarify a bit what type of answers were there in the record when you were referring to these high ratio shortenings in your own mind as basing your answers on. A. My memory of the testimony which had been introduced at the bread standards hearings in 1941 in regard to high ratio shortenings was that evidence had been introduced at that time that high ratio shortenings contained as much as 20 per cent mono- and diglycerides. I had not had time to reread the testimony presented then, but I have been assured by people who should be familiar, more familiar with that testimony than I am, that my impression is erroneous, and that the evidence presented at that time did not indicate that as much as 20 per cent mono- and diglycerides were incorporated in high ratio shortening.
>
> "Q. Well, now, Dr. Bradley, if the prior record referred to such shortenings as containing from 4 to 10 per cent mono- and diglycerides, and that had been your impression *yesterday,* would you have revised then any answers that you gave *yesterday?* A. *I think that the upper limit of the mono- and diglycerides permitted in shortening for use by the bread baker should be determined from experimental evidence, which I am not prepared to present,* and that that upper limit should be determined on the basis of the qualities produced in the finished loaf of bread by shortenings containing various percentages of mono- and diglycerides, when used in the

manner employed by the baker." *A. 707-708.* (Emphasis supplied.)

And in answer to questions by counsel for the Administrator, Dr. Bradley confirmed the admission that his evidence was not probative on the issue of an upper limit for mono- and diglycerides:

> "Q. Concerning the level of monoglyceride in bread shortening, do I understand from your answer to Mr. Mulford that *you do not have enough information to set a hypothetical limit on the amount of mono- and diglycerides desirable in bread shortening? A. Yes, sir, your understanding is correct.*
>
> "Q. Have you made an exacting study of the subject using various monoglycerides combined with various types of triglycerides? A. No, sir.
>
> "Q. Since the standard we are setting includes rolls and buns, do you believe any possible answer should include these products? A. Yes, sir.
>
> "Q In arriving at the answer to this question, do you consider that practical field experience had by operating commercial bakers is important? A. Yes, sir." *A. 708-709.* (Emphasis supplied.)

The "practical field experience by operating commercial bakers" which Dr. Bradley suggested as the proper basis for setting a limit on the use of mono- and diglycerides is not cited by the Administrator and, so far as this record shows, does not exist.

This Court has recently set aside a deception finding made by the Administrator where the sole basis for the finding was the testimony of a witness who had an inadequate foundation for his conclusion. *Cream Wipt Food Products Co.* v. *Federal Security Administrator,* 182 F. 2d

789, 791 (C. A. 3, 1951). Here the Administrator has made a deception finding on the sole basis of testimony which was completely retracted by the witness who gave it.

We have also pointed out that the 20% level is meaningless, since it is tied to a variable—the shortening content of bread. The Administrator suggests that his finding is meaningful in terms of a median level of shortening *Administrator's Brief, p. 65.* But the Administrator did not prescribe a median level of shortening. Any amount is permissible under the terms of his order.* *A. 475.* The basic difficulty is that the hearings did not focus on what the Administrator has since conceived to be the important question of a level of use in terms of "deception". If the issue is important, it deserves more careful treatment in a reopened hearing.

We do not understand the Administrator to say that there is no level at which our products are non-deceptive. He is content with the assertion that the record shows no such level. *Administrator's Brief, p. 62, n. 74.* A similar absence of evidence did not prevent him from finding a non-deceptive level for pure monoglycerides, *A. 461,* and from prescribing such a level for diacetyl tartaric acid esters without bothering to make a finding. *A. 475.* Here again, the Administrator's difficulty arises because the hearings were not guided in conformity with his afterthought that a line can be drawn between deceptive and non-deceptive levels of use.

The Administrator attempts to slough off our additional evidence on the deception issue by picking what he conceives to be flaws in the testing methods. If cross-examination of those methods is necessary, the place for it, we would suggest, is the reopened hearing to which we are entitled.

---

*Thus bread containing 3% of shortening would include .6% of mono- and diglycerides; bread containing 6% of shortening would include 1.2% mono- and diglyceride.

POINT III.

The Administrator has no statutory power to exclude a proposed ingredient as to which he finds there is no definite evidence of injury, on the ground that its proponent has failed to prove that there is "no likelihood of injury" to persons consuming the ingredient over a life span.

In our main Brief (pp. 35-39) we analyzed the specific language, context and legislative history of the food standard provisions of the Food, Drug and Cosmetic Act under which the Administrator acted to bar our products from bread. Section 401. From this analysis we reached the conclusion, and urged it to this Court, that Congress has not authorized the Administrator in food standards proceedings, or otherwise, to exercise the power under which he purports to act here: *i. e.*, the power to exclude from food an ingredient about which there is no definite evidence of injury because its harmlessness when consumed by human beings over a life span has not been conclusively established.

The Administrator purports to restate our argument on this point, but misstates it for purposes of his reply. His counsel has told the Court that we are arguing that "the Administrator cannot take action to exclude a suspect chemical unless the proof shows definite past injury from it." *Administrator's Brief, p. 28.* He then proceeds to argue (as we would agree) that the Administrator does not have to find actual past injury.

What we urged in Point III of our main Brief is that the Administrator's power to exclude an ingredient from a food standard on the ground of safety is no greater than

his statutory power, under the sections concerned specifically with health, to bar that material from the market by injunctive or criminal action. The Administrator is authorized to seize, enjoin the sale of, and prosecute the purveyor of adulterated food. In such a proceeding, it would not be necessary for the Administrator to prove "definite past injury". *Administrator's Brief, p. 28.* It would be necessary only for him to carry his burden of proving either that [redacted] our product was a poisonous or deleterious substance which "may" render bread injurious to health or that our product was a poisonous or deleterious *addition* to bread. Sections 402(a)(1) and (2). So in this food standard proceeding, we contend that an order excluding that ingredient must be based on a minimum *affirmative* finding either that our product *is* poisonous or deleterious and *may* render bread injurious to health, or that it *is* a poisonous or deleterious additive.

The Administrator has made no such finding here.

Even in the *Quaker Oats* case, quoted at length in the Administrator's Brief in this case, the Administrator found *affirmatively* that use of the proponent's products "*would* tend to confuse and mislead consumers." *Federal Security Administrator* v. *Quaker Oats Co.,* 318 U. S. 218, 220 (1942). (Emphasis supplied.) That case did not approve exclusion from a food standard based on a *negative* finding that the proponent had failed to prove that there was no likelihood that its product would confuse and mislead consumers. It is our contention that exclusion on the basis of such a finding would be illegal and unauthorized, not only on the issue of deception but also on the issue of safety.

Here the Administrator has excluded our product on the completely negative, question-begging finding that, while

there was no "definite evidence of injury . . . the results of the pharmacological tests reported do not warrant the conclusion that there is no likelihood of injury from bread containing these substances in the amount proposed to persons consuming it continuously over a life span." (Emphasis supplied.) He did not find that our product is poisonous or deleterious and may be injurious to health. He did not find that our product is a poisonous or deleterious additive.

The statute does not authorize the exclusion of an ingredient from a food standard on the basis of the negative finding which the Administrator has made. Nor has the Administrator been able to buttress his novel contention with apt reference to legislative history or to a decided case.*

---

*In an attempt to supply authority where none exists, the Administrator cites the report of the Select Committee of the House of Representatives, which recently investigated the use of chemicals in foods. H. R. Rep. No. 3254, 81st Cong., 2d Sess. 10 (1951). *Administrator's Brief, p. 28.* Whatever support this Committee opinion might give to an order of the Administrator excluding a food which he determines *may* injure health, the quotation from the Committee opinion does not support an order based on a negative finding that Atlas has failed to prove that there is no likelihood of harm from consumption of its products over a life span. It may also be noted that the Supreme Court has repeatedly refused to accept the opinion of members of a subsequent Congress about legislation enacted by a previous Congress "as authoritative guides to the construction of" that legislation. *United States* v. *United Mine Workers,* 330 U. S. 258, 281-282 (1947); *Fogarty* v. *United States,* 340 U. S. 8, 13-14 (1950). This ruling is especially applicable to a case like the present one where no member of the Committee expressing the opinion was a member either of the Committee which drafted the legislation or of the Congress which enacted it.

POINT IV.

The Administrator has failed to justify his discrimination between our products and the competing products on the issue of safety.

In our main Brief, we pointed out that even if the Administrator possesses the power whose existence we question, his decision to exclude our products while admitting the products of our competitors constitutes a discrimination unsupported by substantial evidence (pp. 40-61). The crucial part of the Administrator's Brief is not the nineteen pages (pp. 35-54) in which he argues that each of his specific findings as to our products is supported by substantial evidence,* but the five pages (pp. 54-58) in which he argues that the *discrimination* between our products and the competing products is supported by substantial evidence.

On page 55 of his Brief, the Administrator attempts to rationalize the distinction drawn. This rationalization consists of four points as to which the Administrator contrasts our principal product sold for use in bread—Myrj 45—with the competing mono- and diglycerides, to the detriment of our product. Each of these distinctions is unsubstantial, as we show below:

A. Period of Use

The Administrator suggests as one ground for the distinction that the mono- and diglycerides have been used in foods for 20 years while our product has only been used since 1947. Actually, the mono- and diglycerides at the

*There is no need to repeat here the answers to that contention made in our main Brief (pp. 40-61).

levels presently permitted have not been in bread for any longer than our product. Their widespread use in bread coincides closely with ours. In any event, continued use for 10 years or for 20 years does not resolve the issue of the cumulative effect of a substance over the life span.

The Administrator attempts to extend the time distinction to include diacetyl tartaric acid esters. He makes the evasive statement that "all of the ingredients in it have been used in food for some time." *Administrator's Brief, p. 57.* The ingredients and the resulting chemical compounds are two entirely different things. The very citation relied on to support this basically irrelevant statement shows that diacetyl tartaric acid esters were developed on a research basis beginning only in 1947 and have a shorter and far less widespread use in the food supply than do our products. *A. 3090-3092.*

B. *"Natural"* v. *"Chemical"* Substances

Another difference relied upon by the Administrator is the assertion that mono- and diglycerides are "closely related" to natural fats while our products are chemicals "closely related" to known poisons. The fact is that mono- and diglycerides are not natural fats, but at best decomposition products of natural fats, while diacetyl tartaric acid esters have no analogue at all in nature. *Tr. p. 11101; A. 431.* Moreover, whether a particular food or chemical substance is "closely related" to another food or chemical substance, as the Administrator's Brief uses that expression, is meaningless in terms of safety; for example, grain alcohol (ethyl alcohol) is "closely related" to wood alcohol (methyl alcohol); glycerol monolaurate (a type of mono- and diglyceride excluded by the Administrator from this very bread

standard) is "closely related" to glycerol monostearate and the rest of the mono- and diglycerides (which are admitted). Furthermore, both our products and the competing products are produced by chemical processes. As a representative of one of the manufacturers has testified, the mono- and diglycerides are produced commercially by chemical reactions in a tank. *A. 115-116.* In the face of this fact, the notion that the Administrator need not inquire into the safety of the mono- and diglycerides because they are "natural" is not a *substantial* basis for the discrimination practiced here.*

The other branch of the Administrator's argument on the "chemical-natural" dichotomy is a contention that polyoxyethylene monostearate "contains residues of poisonous impurities." In our original Brief we showed that even if there were any quantity of ethylene glycol present in Myrj 45, it would amount at most to four parts per million in a loaf of bread. *A. 1970.* We pointed out that if a person ate a whole loaf of bread daily, he would take in less than 0.0009 grams or less than 3/100,000ths of an ounce each day. And the fact remains that there was not even a contention that such a small amount of ethylene glycol could be acutely toxic. Moreover, there can be no question of chronic toxicity. The two characteristic *chronic,* toxic effects from the consumption of harmful amounts of

---

*The Commissioner of Food and Drugs agrees that the distinction is not substantial. "Much confusion has come from the convenient but inaccurate . . . expression 'chemicals in food.' The ineptness of that expression is apparent when we consider that foods themselves are chemicals, and that the living organism which consumes food is itself a complex of chemicals in which uncounted chemical reactions sustained by foods are continuously occurring." Crawford, *The Food and Drug Administration's Viewpoint on Chemicals in Foods.* 7 Food, Drug, Cosmetic Law Journal 85 (1952).

ethylene glycol are (1) excretion of oxalic acid and (2) kidney damage. Neither of these effects has appeared from feeding Myrj 45 to animals.*

C. Metabolic Fate

The Administrator suggests as a third basis for distinction that the mono- and diglycerides are metabolized in the body in the same manner as natural fats, while the metabolic fate of the polyol portion of Myrj 45 is "unknown". Again, the Administrator's counsel says more than the Administrator felt that the evidence permitted him to say. There is not one word in the Administrator's findings to suggest that the metabolic fate of mono- and diglycerides is known. He does, however, suggest that their metabolic fate is known in his memorandum opinion. *A. 479.* But when one examines the few casual references in the record to the metabolic fate of the mono- and diglycerides, it is obvious why the Administrator elected not to make a finding on that issue. *A. 603-606.* Furthermore, the Food Protection Committee of the National Research Council has specifically mentioned the metabolic fate of the mono- and diglycerides as a problem which remains to be answered before a final judgment on their safety can be made. *A. 381.* We submit that it is improper for the Administrator to attempt to use as a basis for distinguishing between our products and the mono- and diglycerides a purported fact which he himself has failed to find, and a question which has been raised with respect both to our products and the competing products.

---

*The Administrator's Brief suggests that eating Myrj 45 caused increases in the oxalic acid content of human urine. This is not apparent from the record references cited by the Administrator, and, as set forth at p. 55 of our main Brief, is negatived by Finding 41. *A. 471.*

Equally untenable is the other branch of the Administrator's argument—the statement of his counsel that the metabolic fate of the polyol portion of Myrj 45 is "unknown". That statement is presumably a paraphrase of the Administrator's memorandum opinion. Yet examination of his memorandum opinion shows no reference at all to the metabolic fate of Myrj 45. *A. 478-484.* And his actual finding on the issue falls far short of the argument now being made. *A. 470.*

D. Proof of Safety

In conclusion, the Administrator's Brief states another ground for discrimination that again goes far beyond his findings or even his memorandum opinion. He says, "on the record, the products [mono- and diglycerides] are safe and no question was raised regarding their safety." "On the record" or "off the record," it is hard to reconcile this statement with the Administrator's admission that the safety of the mono- and diglycerides has yet to be established. *A. 459, 468.* There are two answers to the assertion that no question was raised regarding the safety of the mono- and diglycerides. First, this statement ignores the testimony of Dr. Harrisson and the work done by Braun and Shrewsbury, which showed damage from the feeding of mono- and diglycerides at high levels. *Atlas Brief, p. 51; A. 3216; Exh. 370; Exh. 378.* Second, the Administrator's assertion that no question was raised begs the very question presented by this review proceeding—whether, on this record, the Administrator had the *duty* to raise questions regarding the safety of the mono- and diglycerides once he chose to raise questions about the safety of the Atlas products. In any event, the same questions were authori-

tatively raised about *both* classes of products by the National Research Council *before* the promulgation of the final order in this proceeding. *A. 379-381.* Proponents of mono- and diglycerides and others have admitted before a Congressional Committee that the requisite safety studies have not been conducted. *A. 116-123.* It is consequently improper to include the mono- and diglycerides while excluding our products.

In stating the other side of this final comparison, the Administrator's counsel again goes beyond what the Administrator found and what the record supports when he states that "there are grave doubts" about the safety of our product. If the Administrator had "grave doubts" about the safety of Myrj 45, he did not say so in his findings. His counsel's afterthought that "grave doubts" would be a good argument to raise can hardly contradict the Administrator's considered finding on the record that "the record shows no definite evidence of injury" from the use of our products. It is a far cry from "grave doubts" to the cautiously worded finding that Atlas has not managed to convince the Administrator that "there is no likelihood of injury" from the use of our products in bread over a life span.

The Administrator's counsel also makes the extreme statement that the experimental data on our products "tend to show that polyoxyethylene monostearate is not safe." The Administrator himself found no such thing. If he could have, he presumably would have. His counsel's attempt to stretch the findings into something different from what they actually are is a tacit recognition of the force of our argument that the Administrator had no power to exclude our product on the finding which he actually did make.

Finally, the Administrator's counsel suggests that our Myrj 45 may influence the course of infectious diseases. As we showed in our main Brief, such a possibility is outside the range of fruitful scientific speculation (pp. 57-58). It is, however, typical of the Administrator's entire attempt to justify the discrimination between our products and the mono- and diglycerides that he concludes by mentioning a possibility which, if it did exist for our products, would exist also for the mono- and diglycerides, because such a possibility could only result from surface-activity, a characteristic which the two classes share. *Atlas Brief, p. 57.*

We submit that the Administrator's entire discussion of the safety issue in his Brief (pp. 35-58) is unfounded and fails to justify his discrimination between our products and the competing mono- and diglycerides.

POINT V.

The hearing should be reopened to consider the laboratory experiments on the safety of our products which the Food and Drug Administration has been conducting since 1948.

The Administrator devotes 17 lines of a 72 page brief to his failure to place in the record the safety experiments conducted on the Atlas products by his own expert scientific assistants in the Food and Drug Administration laboratories. *Administrator's Brief, pp. 71-72.* The main burden of his brief discussion is that this evidence is no business of ours—or of the Court's.

It is, of course, perfectly proper for the Food and Drug Administration to conduct such tests on an ingredient proposed for use in a standardized food, *so long as they become*

part of the record on which the decision to include or exclude a food ingredient is made. The free interchange of experimental data between the Food and Drug Administration scientists and the scientists engaged by the proponents of new food ingredients is of great assistance in promoting the program of food technology. Until very recently the Administrator has permitted his scientists to discuss their work on the Atlas products with the scientists engaged by Atlas in accordance with the customs of the profession. The Atlas scientists were advised, among other things, that the Food and Drug Administration's work included the very type of life span multi-level chronic toxicity experiments on Myrj 45 and the other Atlas products which, according to the Administrator's findings and Brief, he considered to be the principal gap in the available safety data on the Atlas materials.

When Atlas filed its petition for review in this Court, however, the scientists of the Food and Drug Administration were forbidden to discuss any phase of the FDA's scientific tests on the Atlas products with the scientists engaged by Atlas. As the Administrator states in his Brief (pp. 71-72), we then urged him to lift this iron curtain and to permit his scientists to advise us as to the status of their tests. Since the Administrator has now called to the attention of the Court our efforts to obtain disclosure, we are reprinting in the Appendix to this Reply Brief the entire correspondence between counsel for Atlas and counsel for the Administrator on this subject. As will be seen from the correspondence, the Administrator has specifically refused to state whether the multi-level chronic toxicity life span experiment on Myrj 45 has been completed, or if not completed, when it will be completed.

Yet, the Administrator has transmitted this same experimental data—withheld from the manufacturer whose products were the subject of the experiments—to the Food Protection Committee of the National Research Council, which is now considering the safety of various classes of surface-active agents in foods. He denies any impropriety in submitting this data to a "distinguished neutral body". *Infra, p. 12a.* We agree with this description of the Food Protection Committee. We believe that the same description would be equally applicable to this Court. But the Administrator refused to give us this material for fear that we would present it to the Court. *Infra, pp. 8a, 12a.*

The Administrator also states in his Brief that before the final order issued, he had before him the Atlas request to reopen the hearing to consider the Food and Drug Administration's own work. He explains that he "asked the Food and Drug Administration if it had any results of tests that would settle the question of safety", and "was informed that the Administration had no such data." *Administrator's Brief, pp. 71-72.*

The issue of whether the Food and Drug Administration's experimental work would "settle" the question of safety is one to be determined by examination of the tests in a reopened hearing and is not for the Administrator or the Food and Drug Administration to determine *ex parte.* It is clear that these tests comprise an important body of scientific data which should properly be a part of the record on which the administrative decision to admit or ban a product is made. The Administration itself has stated that during the course of the extensive tests it has undertaken since 1948, over one thousand animals of several species

have been tested with a wide range of diets to which "synthetic emulsifying agents" were added.*

If the Administrator continues his refusal to inform this Court by placing on the record exactly what data the Food and Drug Administration did have on May 12, 1952, and exactly what data it has today, the Administrator will effectively prevent this Court from performing its proper review function. Two vital questions before this Court are whether:

(a) On May 12, 1952 the Food and Drug Administration's chronic toxicity life span tests or experiments on Myrj 45 were so nearly complete and of such importance that the record should have been reopened to consider this work; and

(b) At the present time the Food and Drug Administration's chronic toxicity life span tests or experiments on Myrj 45 have been completed or are so nearly complete and of such importance that the record should be reopened to consider this work.

If this Court does not know the status of the Food and Drug Administration's own experimental work on May 12, 1952 because the Administrator refuses to tell us or to tell this Court, this Court cannot decide whether the Administrator acted properly in refusing to reopen the record on May 12, 1952. If this Court does not know the status of the Food and Drug Administration's work at the present time because the Administrator refuses to tell us or to tell this Court, this Court cannot decide whether to order the

*Annual Report of the Federal Security Agency, Food and Drug Administration 17 (1951).

Administrator to reopen the record now under Section 701 (f)(2) of the Food, Drug and Cosmetic Act.

CONCLUSION.

The essential issue in this case is whether the Court should set aside the Administrator's order insofar as it excludes the Atlas products from bread and should at the same time direct that the record be reopened.

We believe we have shown that, without regard to any evidence outside the record, the Administrator has made errors of law and illegally discriminated in excluding the Atlas products on both the issue of deception and the issue of safety.

We further contend that apart from the need to correct plain errors on the existing record, the record should be reopened to consider the important new evidence which not only makes the existing record hopelessly stale, but confirms the illegally discriminatory nature of the Administrator's findings. For example, the hearing should be reopened to take evidence on the possible relationship of deception, if any, to levels of use of the Atlas products and competing products, a question on which the existing record is completely barren of any evidence because neither the Government nor any party to the proceeding focused on the question at the time the hearing was held. There should also be evidence, such as we have offered, making direct comparisons between bread baked with the various types of surface-active agents, both in terms of scientific measurement of rates of firming and in terms of actual consumer reactions.

The hearing should also be reopened to permit the introduction of, and cross examination with respect to, the new safety evidence developed by Atlas and by the manufacturers of diacetyl tartaric acid esters (on the basis of which those products have been admitted to the standard), as well as the extensive and unreported tests conducted by the Food and Drug Administration itself.

In asking the Court to reopen the record for the taking of this important new evidence,* we rely on the explicit statutory direction of Section 701 (f)(2) of the Food, Drug and Cosmetic Act that:

> "If the petitioner applies *to the Court* for leave to adduce additional evidence, and shows *to the satisfaction of the Court* that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceedings before the Secretary [now the Administrator], *the Court may order* such additional evidence . . . to be taken before the [Administrator] . . ." (Emphasis added).

In his brief, the Administrator contends that this Court can reverse his refusal to reopen the record only on a showing that the Administrator abused his "discretion." The words of the statute are the short answer to this contention. The statute gives discretion to the *Court* to determine whether a record should be reopened. There was no need under the statute to request the Administrator to reopen the hearing. Consequently, a previous refusal by the Administrator to reopen the record is neither binding nor necessarily persuasive. Since the Food, Drug and Cosmetic Act leaves the question of reopening to the Court, the Ad-

*Petition for Review, p. 16.

ministrator's citations of cases reviewing Interstate Commerce Commission orders, where such a statutory provision as Section 701(f)(2) is not applicable, are beside the point. In the ICC cases, as Mr. Justice Jackson points out, "it has been considered that the discretion to be invoked was that of the body making the order, and not that of the reviewing body." *Interstate Commerce Commission* v. *Jersey City,* 322 U. S. 503, 515, 64 S. Ct. 1129, 1135 (1944). Any other rule would mean that an administrative denial of a motion to reopen completely ousts this Court's jurisdiction under Section 701 (f)(2).

If the Court agrees that it should remand this proceeding for the purpose of correcting the substantial errors committed by the Administrator in light of the existing record or for the purpose of taking important new evidence, or for both reasons, it would be both necessary and appropriate for the Court to continue to stay that part of the Administrator's order which excludes Atlas products from bread. A stay is necessary to prevent irreparable harm, as we demonstrated in our Motion for a Stay, and as this Court agreed in granting the stay. A stay would be appropriate because a finding that the Administrator has committed errors means that the exclusion of the Atlas products from bread is illegal, and because of the prima facie showing that the new evidence to be taken at a reopened hearing will establish both the discrimination inherent in excluding Atlas products from bread and the affirmative propriety of permitting the use of Atlas products as an optional ingredient.

The only unusual factor here is a suggestion that the public health is in danger. Considering the suggestions of danger to public health at face value, however, it is our earnest belief that there is absolutely no risk to the public

from a stay of the Administrator's order pending a further hearing. The best evidence of this fact is that, although our products have been widely consumed for almost six years, not a single example of injury to humans has appeared. The danger at which the Administrator hints is a possibility of harm from consumption of the products in question over a life span. If the Administrator had evidence, or even responsible opinion, that the public health would be jeopardized by continued consumption of our products for the period necessary to complete the hearings, it surely would have been presented and the Administrator surely would not have allowed thirty-two months to elapse between the end of the hearing and publication of his order. Furthermore, if the Administrator really believes that continued consumption of our products may injure health, or if after this Court orders a new hearing the Administrator concludes that health is in jeopardy, he has available ample remedies to protect the public. On the other hand, we have previously submitted to the Court in support of our application for a stay pending review, affidavits of distinguished scientists averring that in their opinion there is no more danger to the public health, long range or short, from continued consumption of our products than from the consumption of the competing products which the Administrator has admitted pending final proof of their safety.

The Administrator's bread standard has been in effect since August 13, except for its exclusion of our product from bread. A continuation of the stay already granted by this Court will not affect the future operation of the standard. But a continuation of the stay will enable the Admin-

istrator to do what he has not done—to perform his duties equitably, legally and without discrimination.

Respectfully submitted,

OSCAR COX

1210 18th Street, N. W.
Washington 6, D. C.
Attorney for Petitioner

C. C. GAMMONS,
KENNETH E. MULFORD,
ROGER R. HORTON,
Delaware Trust Co. Bldg.,
Wilmington, Delaware.
LLOYD N. CUTLER,
LOUIS F. OBERDORFER,
HERBERT L. PACKER,
DONALD F. TURNER,
1210 18th Street, N. W.,
Washington 6, D. C.,
Of Counsel.

APPENDIX

Letterhead of

COX, LANGFORD, STODDARD & CUTLER

July 9, 1952

Hon. Oscar R. Ewing
Federal Security Administrator
Washington 25, D. C.

Re: *Atlas Powder Company* v. *Ewing*

Dear Mr. Ewing:

As you know, Atlas Powder Company has petitioned the Court of Appeals for the Third Circuit to review your order issued May 12, 1952, establishing a standard of identity for bread and rolls, insofar as that order prohibits the use in bread and rolls of certain surface-active materials manufactured by Atlas Powder Company.

The Atlas materials used in bread are members of a general group of materials manufactured by Atlas and used in a number of other food products, including ice cream. For the past several years, Atlas has been sponsoring an extensive program of scientific studies designed to determine whether there is any reasonable likelihood of injury from the use of Atlas materials to persons consuming these materials regularly over a life span in the amounts in which they are used in various foods.

These studies are being continued despite the fact that Atlas believes, as a result of studies already completed, that it has already established the safety of its materials. The studies are being continued in order to convince the Food & Drug Administration, the Food Protection Committee of the National Research Council, and other interested scientific bodies that our materials can be safely and beneficially used in foods. In the very nature of things, these studies may

never be "completed" in any final sense, but may continue for some time. The number of questions which recent scientific developments have raised and can continue to raise about any and all food ingredients is likely to outstrip even the developing capacity of modern scientific techniques available to answer these questions.

The Atlas-sponsored studies are being conducted by various eminent and independent scientists at university and private laboratories throughout the country, with the cost of the work, of course, being assumed by Atlas. The studies being conducted are of the general types recommended by Dr. Lehman and his associates in the Food & Drug Administration, both in general publications relating to testing procedures for all food ingredients and in specific discussions with members of the Atlas scientific staff as to desirable studies for the Atlas materials. Most of the independent scientists engaged to conduct these studies have at our suggestion discussed both the original plan and the subsequent progress of their work with Dr. Lehman and his staff.

These meetings and conversations at the scientific level have, of course, involved a general and frank exchange of detailed information as to the progress of scientific experiments and the interpretation of particular data, including experiments being conducted and data being compiled by the Food & Drug Administration laboratories in their own experiments on the Atlas materials. This is the generally accepted custom in all fields of scientific research. It has been of great benefit to the Atlas scientific staff and to the independent scientists engaged by Atlas in planning and directing the course of the Atlas-sponsored experiment program. We hope that these meetings have also been of benefit to the Food & Drug Administration's scientific staff in planning and directing their own experiments on the Atlas materials and in furnishing expert scientific advice to the Food & Drug Commissioner and to you.

This free exchange of information and the mutual discussions to plan experiments, report results and interpret data were abruptly terminated shortly after Atlas advised the Food & Drug Administration of its intention to file a petition for review of the Federal Security Administrator's order, published in the *Federal Register* for May 15, 1952, establishing a standard of identity for bread and rolls. Both the Food & Drug Administration scientists and the Commissioner of Food & Drugs himself advised us that the decision to terminate the free interchange of scientific information was made on recommendation of your General Counsel's office because of the fact that the parties were "in litigation."

In subsequent discussions with your General Counsel, Mr. Alanson Willcox, he has advised us in substance that the reason for this recommendation was that one ground cited in support of our petition for review is your failure to reopen the record to consider the results of certain long-term chronic toxicity experimental studies of the Atlas materials which had recently been conducted by the Food & Drug Administration's staff. He stated that the scientific discussions had been terminated because Atlas might choose to call to the attention of the Court information as to these chronic toxicity tests obtained as a result of continuing the discussions. Mr. Willcox stated that in his opinion it would be improper to call to the Court's attention any information dealing with events occurring after May 15, 1952, and that the best way of preventing Atlas from calling such information to the Court's attention would be to deny the information to Atlas by shutting off the scientific discussions.

We advised Mr. Willcox that we desired to have the scientific discussions continue for reasons unconnected with the present Court action. We pointed out that we have gone to great expense to finance independent scientific experiments for the purpose of obtaining expert opinions from independent scientists as to the safety of our materials, and

that these scientists could hardly be expected to express their opinions when highly pertinent scientific information available in the field was being denied to them and when they are forbidden to discuss the subject with Government experts.

We also pointed out that in the immediate future the independent scientists working on Atlas-sponsored programs will be called upon to present their work and their opinions to the Food Protection Committee of the National Research Council, that the National Research Council will probably also be receiving data and opinions from the staff of the Food & Drug Administration, and that the independent scientists engaged in the Atlas experimental program will thus be in the position of presenting data to the Food Protection Committee which the Food Protection Committee will be comparing with secret data and opinions received from the Food & Drug Administration, of which these independent scientists have no knowledge and which they have been forbidden to discuss with the Government scientists who did the work.

We pointed out that this method of conducting scientific research and arriving at scientific conclusions is at variance with recognized and accepted scientific procedures in all but the most highly classified military fields; that it is at variance with the Food & Drug Administration's own established policy of freely discussing and exchanging scientific data with interested manufacturers and outside scientists; and that it can be interpreted as a reprisal against the Atlas Powder Company for exercising its legal right to seek a Court review of a food standard order, and for raising with the Court the perfectly legitimate question of whether it was erroneous to refuse to reopen the record in order to consider important work on the Atlas materials recently performed in your laboratories. In the long run, a policy of nondisclosure can only retard the progress of scientific knowledge on this imoprtant subject, a result which can hardly be viewed as in the public interest.

We also pointed out that while our major objective in requesting a resumption of scientific discussions was not related to the current appeal, we could not properly agree, as a condition of resuming these discussions, that we would refrain from calling to the attention of the Court any pertinent information which might result from these discussions, and which might be relevant to the issues in the present appeal. If these discussions would lead to the disclosure of information that is relevant to the issues involved in the present appeal, we believe that you yourself would not want to be in the position of withholding such information from the Court. If we believe the information is relevant and can properly be called to the Court's attention, and your legal advisors disagree as to the relevancy of the information or as to whether the Court can properly take notice of such information in the present posture of the appeal, we believe that any such disagreement can safely be left to the judgment of the Court.

At the end of our conference with Mr. Willcox, he requested us to submit a specific request in writing, stating the exact nature of our request and also setting forth any conditions to which we might agree for withholding from the Court any information obtained during such discussions.

Our specific requests are as follows:

1. We request that Dr. Lehman and his staff be authorized to carry on scientific discussions with the scientific staff of the Atlas Powder Company and independent scientists carrying on Atlas-sponsored experimental studies, in the same manner and with the same freedom of exchange that existed before May 15, 1952.

2. If this request is denied, we request that we be advised in writing of the current status of the long-term chronic toxicity feeding studies conducted on Myrj 45, Span 60 and Tween 60 by the laboratories of the Food & Drug Administration, including the following specific information separately stated as to each material:

(a) When the studies began.

(b) When the feeding of the animals terminated or is scheduled to terminate.

(c) A description of the number of animals used, the level fed, the make-up of the diet and other relevant conditions of the experiment.

(d) The results observed during feeding period, such as weight and general physical condition.

(e) The results of any autopsies, histologies, or other post-feeding work conducted to date.

(f) The present interpretation of the scientists conducting the experiments as to the meaning of the results.

(g) The date of completion of the study, or the scheduled date of completion.

(h) The date of completion of the written report describing the study, or the scheduled dated of completion.

(i) Copies of whatever data relating to these studies has been submitted to the Food Protection Committee of the National Research Council.

3. If request 2 is denied, we respectfully request the same information as of May 15, 1952.

We have to advise you that we cannot agree to any conditions to be placed upon the use in the present review proceedings of any information obtained pursuant to the above requests. In the event we elect to call any such information to the attention of the Court, and you believe that such information should not properly be placed before the

Court, we would expect you to present your objections to the Court. We believe the Court will resolve any such question in a manner which fully protects the rights of the Government.

Sincerely yours,

(s) Cox, Langford, Stoddard & Cutler
Cox, LANGFORD, STODDARD & CUTLER
Attorneys for Atlas Powder Company

FEDERAL SECURITY AGENCY

WASHINGTON

July 16, 1952

Office of the
Administrator

General Counsel

Dear Mr. Cox:

I have discussed with Mr. Ewing your letter of July 9 to him, and he asked me to convey to you his decision on the matter.

If during the pendency of the litigation the investigatory work of the Food and Drug Administration should develop facts which caused Mr. Ewing to believe that your client's products are safe for use in bread, he would of course feel obligated to call that development at once to the attention of the Court. Except for that possibility, Mr. Ewing agrees with the view I have expressed to you orally, that any further discussions between the scientists of your client and those of the Food and Drug Administration should be postponed until after the conclusion of the litigation.

Our purpose is to protect the public interest, as we see it, by bringing the present litigation to an end, and thus securing removal of inadequately tested materials from bread, at the earliest possible time.

Investigations by the Food and Drug Administration of the safety of Myrj 45, Tween 60 and Span 60 have not yet been completed, and I am told will not be completed until some time in 1953. That being the case, what you are asking is that we enable you to present to the Court, at second hand, the results of uncompleted work

of our scientists, from which they are not yet ready to draw conclusions. I do not think that is a reasonable request.

Sincerely yours,
/s/ Alanson W. Willcox
Alanson W. Willcox
General Counsel

Mr. Oscar Cox
Cox, Langford, Stoddard & Cutler
1210 18th Street, N. W.
Washington 6, D. C.

Re: *Atlas Powder Company* v. *Ewing*

Letterhead of

COX, LANGFORD, STODDARD & CUTLER

July 18, 1952

Alanson W. Willcox, Esq.
General Counsel
Federal Security Agency
Washington 25, D. C.

Re: *Atlas Powder Company* v. *Ewing*

Dear Mr. Willcox:

We have received your letter of July 16, 1952 advising that the Administrator has denied our request to lift the ban on free scientific interchange which you have imposed on the scientists employed by the Food and Drug Administration.

Your letter states as a reason for denying our request that investigations by the Food and Drug Administration of the safety of Myrj 45, Tween 60 and Span 60 have not yet been completed and will not be completed until some time in 1953. The principal Atlas material used in bread is Myrj 45. We had previously been informed that the two-year chronic toxicity test on Myrj 45 had been completed. Although our letter of July 9 specifically asks whether this information as to the Myrj 45 tests is correct, your reply groups the work on Myrj 45, Span 60 and Tween 60 together, and does not specifically state whether all or part of the work on Myrj 45 alone is completed. We therefore respectfully renew our questions as to the status of the work on Myrj 45.

Your letter does not deal specifically with the detailed requests contained in our letter of July 9, 1952, but rejects all of them as "unreasonable". One of the requests was for copies of whatever data the Food and Drug Administration has submitted to the National Research Council concerning the safety of our products. Unless we have been mis-

informed, at least some of the Food and Drug Administration's data on our materials has recently been submitted to the National Research Council. It would therefore appear that the work of your scientists is not completely unevaluated and it would further appear that to some extent your scientists are "ready to draw conclusions." We therefore do not see how a request for the data you have submitted to the National Research Council can possibly be considered unreasonable, and we respectfully renew that request for your consideration.

Sincerely yours,

OSCAR COX

FEDERAL SECURITY AGENCY
WASHINGTON
July 28, 1952

Office of
The Administrator
General Counsel

Dear Mr. Cox:

I have your letter of July 18 with further reference to your request to continue discussion between the scientists of your client and those of the Food and Drug Administration.

The statement in my letter of July 16, that investigations by the Food and Drug Administration of the safety of Myrj 45, Tween 60 and Span 60 have not been completed, was intended to apply to each of the products separately as well as to the group. In the case of each product, some individual tests have been completed, some are in process, and some are in contemplation which have not yet been started. All of this work is expected to shed light, among other things, on the safety of the products in question, and it is not correct to speak of any particular completed test as resolving this issue.

I see nothing inconsistent with the foregoing in the fact that the Food and Drug Administration has submitted data to the National Research Council, nor any implication from such submittal that we have reached any conclusions. Nor do I see any impropriety in submitting to a distinguished neutral body uncompleted materials which we are not willing to submit to your client for presentation to the Court.

Sincerely yours,

/s/ Alanson W. Willcox
General Counsel

Mr. Oscar Cox
Cox, Langford, Stoddard & Cutler
1210 18th Street, N. W.
Washington 6, D. C.

Re: *Atlas Powder Company* v. *Ewing*